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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,528	05/22/2001	Daniel W. Nebert	91830.0476945	1421

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FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, OH 45202-4182

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	09/863,528	NEBERT, DANIEL W.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Valarie Bertoglio. (3) Nicole Tepe.
 (2) Stephen Albainy-Jenei. (4) Daniel Nebert.

Date of Interview: _____.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.
 If Yes, brief description: see attached.

Claim(s) discussed: 1 and 18.

Identification of prior art discussed: _____.


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



 Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: It was agreed that the term "transgenic" encompasses chimeric animals and the claims are enabled with specific respect to chimeras. The terminology "known standard" was discussed as it is not defined by the specification and certain interpretations are not supported by the specification. Applicant agreed to amend the method claims to define the "known standard" and will point to support for the claim amendments in the specification. It was agreed that claim 18 is confusing as it includes both gene names and response elements and that gene names should be spelled out in full as some abbreviations are ambiguous .



Ohio
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PATENT**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Applicant: Nebert : Paper No:
Serial No. 09/863,528 : Group Art Unit: 1632
Filed: May 22, 2001 : Examiner: Valerie E. Bertoglio
For: **TRANSGENIC ANIMALS FOR MONITORING WATER QUALITY**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Ms. Bertoglio

In anticipation of the interview regarding the above-referenced application scheduled for November 3, 2005 at 10:00 AM, below are topics to be discussed and proposed amendments to the application.

AGENDA FOR TELEPHONE INTERVIEW WITH EXAMINER

1. Overview of the Invention
2. The enablement requirement with respect to the predictability of transgene activity/ "known standards" term in Claims 1 and 2.
2. The nature of the transgene as it is expressed in the host organism: stable vs. transient transfection.
3. Nomenclature: The Examiner rejects claim 18 on the basis that the claim is not enabling because the acronyms do not accurately describe the gene/response element, and the acronyms are not properly identified on the website offered by the Applicant.
4. Response Elements: Claim 18 was rejected as being indefinite for defining a group as consisting of "response elements" but including gene names in the group. This is addressed by the proposed amendment below.

PROPOSED AMENDMENTS

Claim 1. A method of measuring contaminants in water comprising:

a. introducing into an aquatic organism a DNA construct comprising a sequence encoding at least one regulatory response element operatively linked to a DNA molecule comprising at least one reporter gene such that the at least one regulatory response element controls the expression of the at least one reporter gene and thereby forming an operative transgenic organism.

b. determining baseline reporter gene expression in the transgenic organism by detecting reporter gene expression in a water sample without contaminant

c. standardizing the transgenic organism by detecting reporter gene expression after exposure of the transgenic organism to a water sample with a known concentration of contaminant, thereby creating a known standard for that organism

- d. ~~b.~~ exposing the transgenic organism to a water sample to be tested for a time sufficient to allow contaminants to become bioconcentrated within the transgenic organism;
- e. ~~e.~~ exposing the transgenic organism to conditions permitting expression of the at least one reporter gene; and
- f. ~~d.~~ detecting the expression of the at least one reporter gene; and
- g. ~~e.~~ correlating the detected expression to the known standards and thereby determining the quantity of contaminants in the water sample.

Claim 2: parallel amendment to that of Claim 1 so as to include standardization language

OR:

Claim 1. A method of measuring contaminants in water comprising:

- a. introducing into an aquatic organism a DNA construct comprising a sequence encoding at least one regulatory response element operatively linked to a DNA molecule comprising at least one reporter gene such that the at least one regulatory response element controls the expression of the at least one reporter gene and thereby forming an operative transgenic organism.
- b. exposing the transgenic organism to a water sample to be tested for a time sufficient to allow contaminants to become bioconcentrated within the transgenic organism;
- c. exposing the transgenic organism to conditions permitting expression of the at least one reporter gene; and
- d. detecting the expression of the at least one reporter gene; and
- e. correlating the detected expression to previously determined reporter gene expression in response to known concentrations of contaminants ~~known standards and~~ thereby determining the quantity of contaminants in the water sample.

Claim 18: The method according to claim 4 wherein the DNA construct contains at least ~~one gene encoding for at least one~~ response element selected from the group consisting of....[list full names of response elements only]

Additional Claim: The method according to claim 4 wherein the DNA construct contains at least one upstream region constituting a response element from the group consisting of....
[list full names of genes only]

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